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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/888,757	06/25/2001	John E. Ahern	B0410/7282D1	2885	
22832	22832 7590 06/29/2005		EXAM	XAMINER	
KIRKPATRICK & LOCKHART NICHOLSON GRAHAM LLP (FORMERLY KIRKPATRICK & LOCKHART LLP)			WILLIAMS, CATHERINE SERKE		
75 STATE ST			ART UNIT	PAPER NUMBER	
BOSTON, M	A 02109-1808		3763		

3763

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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		Application No.	Applicant(s)	•			
Office Action Summary		09/888,757 (	AHERN ET AL.				
		Examiner	Art Unit				
		Catherine S. Williams	3763				
Period f	The MAILING DATE of this communication apports or Reply	pears on the cover sheet wi	th the correspondence address				
THE - External control	MORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. ensions of time may be available under the provisions of 37 CFR 1.1 r SIX (6) MONTHS from the mailing date of this communication. e period for reply specified above is less than thirty (30) days, a repl D period for reply is specified above, the maximum statutory period for reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing the patent term adjustment. See 37 CFR 1.704(b).	I36(a). In no event, however, may a r ly within the statutory minimum of thin will apply and will expire SIX (6) MON e, cause the application to become AB	eply be timely filed y (30) days will be considered timely. THS from the mailing date of this communication ANDONED (35 U.S.C. § 133).	<b>1.</b>			
Status							
1)⊠	Responsive to communication(s) filed on 23 N	March 2005.					
•	·	s action is non-final.					
3)	ers, prosecution as to the merits is	;					
-/ت	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposit	tion of Claims						
5)□ 6)⊠ 7)□	Claim(s) <u>19-32</u> is/are pending in the application 4a) Of the above claim(s) <u>19</u> is/are withdrawn to Claim(s) is/are allowed.  Claim(s) <u>20-32</u> is/are rejected.  Claim(s) is/are objected to.  Claim(s) are subject to restriction and/or	from consideration.					
Applicat	tion Papers						
9)[	The specification is objected to by the Examine	er.					
10)[	10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
	Applicant may not request that any objection to the	drawing(s) be held in abeyar	nce. See 37 CFR 1.85(a).				
11)	Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex	- · ·		d).			
Priority	under 35 U.S.C. § 119						
a)	Acknowledgment is made of a claim for foreign All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Burea See the attached detailed Office action for a list	ts have been received. ts have been received in A prity documents have been u (PCT Rule 17.2(a)).	pplication No received in this National Stage				
Attachmer	nt(s)	_					
	ce of References Cited (PTO-892)		Summary (PTO-413) s)/Mail Date				
3) 🔯 Info	ce of Draftsperson's Patent Drawing Review (PTO-948) rmation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) er No(s)/Mail Date 4/7/05;2/19/02.	——————————————————————————————————————	nformal Patent Application (PTO-152)				

#### **DETAILED ACTION**

# Information Disclosure Statement

The examiner reviewed the parent application and it's contents for the references on 1449 dated 4/7/05. Only three foreign references were found in the parent application. Those references have been reviewed and initialed on the 1449 dated 4/7/05, copy enclosed. However, the remainder of the foreign references on the 1449 dated 4/7/05 are not contained the parent application file and have not been reviewed. It is requested that applicant forward copies of these references from their files for review upon the next action.

### Claim Objections

Claims 31-32 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 31 recites the limitation of "means for receiving" which seems be a second positive recitation of the delivery chamber of claim 20, albeit different wording. Claim 32 positively recites "a port" which is assumed to be the same port as positively recited in claim 20. The examiner is assuming applicant is not invoking 112 6<sup>th</sup> paragraph and means plus function interpretation for the claim limitation since applicant has not stated such and since claim 31 recites sufficient structure including "an arcuate shape".

However, the instant specification including the drawings does not explicitly set forth the means for receiving. In applicant's response dated 3/23/05, applicant pointed to page 8 line 3 to page 10 line 13 for identification of the structures of the "means for receiving". These pages of

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the instant specification give a broad outline of the entire instant device and do not distinctly identify the "means", i.e. structures. Additionally, applicant added new claim 32 to further identify that the "means for receiving" includes "a port formed from...fingers".

In assessing applicant's arguments, the drawings and new claim 31, one can only conclude that applicant intends the "means for receiving" to include the structure of the delivery chamber, the port and the fingers. Having identified these structures as constituting the "means", these dependant claims now positively introduce structures already positively introduced in independent claim 1 and in doing so fail to further limit the claims. It is suggested that either these claims be made into new independent claims or the recitations be re-worded to refer back to the positive recitations in the independent claims.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-23-26, 29 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemelson (US Pat# 4,578,061). Lemelson discloses an elongate flexible body (70A), a delivery chamber/means for receiving (chamber in element 86) with a space and a port, and an actuator (90). The device also includes a control mechanism (93) and a plunger (90). The device is disclosed for use in arteries; therefore, its diameter is dimensioned small enough to traverse the vessels leading from the heart of a patient thereby making it small enough to enter

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the larger atrium and/or ventricles of the heart. See 8:23-52. The delivery chamber, as shown in figure 6 is substantially a cylindrical housing which is dimensioned to store a plurality of minispheres. Even though only one implant is shown within the delivery chamber, the length of the chamber clearly shows that the chamber is capable of housing multiple smaller implants in axial alignment. The implant may be "implanted into the tissue adjacent said head when the latter is disposed at a given location in a body duct, such as an artery, the intestine, throat or other body duct". See Summary 1:10+. A pointed distal end (94) is shown in figure 6 that has a hypodermic construction that would facilitate penetrating tissue. The distal end of the device in figure 6 has an arcuate shape. The device includes a steering mechanism (92,93).

Claims 27-28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson in view of Leschinsky et al (US Pat# 5,873,499). Lemelson meets the claim limitations as described above but fails to include a ratchet assembly, a threaded plunger or a lever-action handle.

However, Leschinsky discloses a dispensing gun that includes a plunger (92) that may be threaded, notched (ratchet) or grooved (ratchet). The gun also includes a handle (62) that has a trigger (104) and a pawl (108).

At the time of the invention, it would have been obvious to substitute the threaded plunger of Leschinsky for the actuation assembly and plunger of Lemelson; and the handle, trigger and pawl of Leschinsky for the control mechanism of Lemelson. Both prior art references are analogous in the implant dispenser art and are also analogous with the claimed invention; therefore, a combination is proper. Additionally, it is well known in the art that

trigger mechanisms with threaded or ratcheted dispenser mechanisms are more stable than hand actuated dispensing mechanism, such as the one by Lemelson. Therefore, the motivation for the combination would have been in order to enhance the control of the dispensing of the implant of Lemelson thereby increasing the safety of the device to the patient.

# Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

#### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. USPNs 5,845,646; 5,322,510 and 4,861,336 teach similar inventions.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine S. Williams June 13, 2005

NICHOLAS D. LUCCHESI SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700